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Synopsis for Ph.D. Ayurved (Kaumarbhritya)

TOPIC

CLINICAL STUDY ON EFFICACY OF YASHTYADI GHRITA IN THE MANAGEMENT OF BALSOSHA (MARASMUS) -- SINGLE ARM OPEN LABEL STUDY

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Through: Proper channel

Sub: - Submission of Synopsis of PhD (Vidyavaridhi) in Ayurveda for registration

Respected sir,

Here with I am enclosing the brief note of my supposed work for the degree of PhD to be carried out under the guidance of Dr. Prem Prakash Vyas Associate professor & Head, P.G. Department of Kaumarbhritya, University College of Ayurved, Dr.S.R. Rajasthan Ayurved University, Jodhpur. The details are as under: -

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Language of Thesis	:	English
Thesis title	:	**Clinical Study on Efficacy of Yashtyadi Ghrita in The Management of Balsosha (Marasmus)- - Single Arm Open Label Study**

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CLINICAL STUDY ON EFFICACY OF YASHTYADI GHRITA IN THE MANAGEMENT OF BALSOSHA (MARASMUS) -- SINGLE ARM OPEN LABEL STUDY

INTRODUCTION

Malnutrition is the condition that results from eating a diet in which certain nutrients are lacking, in excess (too high in intake), or in the wrong proportions.[1,2] The verb form is "malnourish"; "malnourishment" is sometimes used instead of "malnutrition". A number of different nutrition disorders may arise, depending on which nutrients are under- or over-abundant in the diet. In most of the world, malnutrition is present in the form of under-nutrition, which is caused by a diet lacking adequate calories and protein[3,4] —not enough food, and of poor quality. The World Health Organization (WHO) has reported hunger and related malnutrition as the greatest single threat to the world's public health.[5,6] Improving nutrition is widely regarded as the most effective form of aid.[6,7] According to the WHO, malnutrition is estimated to contribute to more than one third of all child deaths, although most often it is not listed as the direct cause.[8] Nutrition-specific interventions, which address the immediate causes of under nutrition, have been proven to deliver among the best value for money of all development interventions. Malnutrition limits development and the capacity to learn. It also costs lives: about 50 per cent of all childhood deaths are attributed to malnutrition. In India, around 46 per cent of all children below the age of three are too small for their age, 47 per cent are underweight and at least 16 per cent are wasted. Many of these children are severely malnourished. The prevalence of malnutrition varies across states, with Madhya Pradesh recording the highest rate (55 per cent) and Kerala among the lowest (27 per cent).[9] Malnutrition in children is not affected by food intake alone; it is also influenced by access to health services, quality of care for the child and pregnant mother as well as good hygiene practices. Girls are more at risk of malnutrition than boys because of their lower social status. Malnutrition in early childhood has serious, long-term consequences because it impedes motor, sensory, cognitive, social and emotional development. Malnourished children are less likely to perform well in school and more likely to grow into malnourished adults, at greater risk of disease and early death. Around one-third of all adult women are underweight. Inadequate care of women and girls, especially during pregnancy, results in low- birth weight babies. Nearly 30 per cent of all newborns have a low birth weight, making them vulnerable to further malnutrition and disease.

Emergency measures include providing deficient micronutrients through fortified sachet powders or directly through supplements.[10,11] WHO,UNICEF and the UN World Food Programme recommend community management of severe acute malnutrition with ready-to-use therapeutic foods, which have been shown to cause weight gain in emergency settings.[12] The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), a member of the CGIAR consortium, partners with farmers, governments, researchers and NGOs to help farmers grow nutritious crops, such as chickpea, groundnut, pigeon pea, millet and sorghum. This helps their communities have more balanced diets.[13]

NEED OF STUDY

Childhood undernutrition accounts for 45% of under 5 mortalities alone and poses a key public health challenge in India. It is a major global health problem, resulting in childhood morbidity,

mortality, impaired intellectual development, suboptimal adult work capacity, and increased risk of diseases in adulthood.[14]

The National Family Health Surveys (NFHS) are nationwide surveys conducted with a representative sample of households throughout the country. The Ministry of Health and Family Welfare (MOHFW), Government of India (GOI), initiated the NFHS surveys to provide high quality data on population and health indicators. The National Family Health Surveys are a major landmark in the development of a demographic and health data base for India. The National Family Health Survey (NFHS-3) have been done in year 2005-2006.The NFHS-3 data shows that 48% of children under age of 5 years are stunted and 20% of children under age of 5 years are wasted. 43% of children under age of 5 years are underweight for their age.

The majority of children suffering from under nutrition (80%) are the mild and the moderate forms which go unnoticed.[15] According to recently released NFHS-4 carried out in 2015-2016 43% of India's children under the age of five are underweight,38.4% are stunted and 21% are wasted. A recent report reveals that in introduction Rajasthan 36.7% of children under the age of five are underweight, 39.1% are stunted and 23.0% are wasted.[16]

Marasmus is the most prevalent form of malnutrition and the most important nutritional disease in developing countries. Deficiency of energy-giving foods predominates over protein deficiency. Its origin may be primary, due to insufficient food intake, often associated with infectious or parasitic diseases, or secondary, due to other conditions that interfere with the absorption or assimilation of nutrients. It contributes significantly to high rates of morbidity and mortality in childhood. It is now recognized as a public health problem, and action to reduce its extent is the responsibility of government nutrition policies and health personnel.

Marasmus is very well described in *Ayurveda* under the heading of *Balsosha*.[17,18] Main etiology behind *Balsosha* is vitiated *Kapha dosha* (humors) which ameliorate *Agni* (digestive power) that enable to form proper rasa dhatu and create ama which block channels, ultimately lead to Balsosha.[14] *Ayurveda* recommended numerous herbal drugs in single or compound form which is not only bring homeostasis in vitiated doshas but also normalize their *Agni* (digestive power) so that child recover speedy. It is need of the hour to provide a solution that is cost-effective and within the reach of a majority of targeted population of low socio-economic status. To keep all these things in mind author, select *Yashtyadi Ghrita*[17,18] mentioned in the management of Balsosha in *Balaupcharaniya* chapter of *Astanaga Samgrha Uttarasthan* which is very nutritious, processed into ghrita form to increased palatability in children.

Properties of trial drugs

Pharmacodynamic properties of herbal drugs which will be used in formulation of *Yashtyadi Ghrita* shows *Madhura, Tikta and Kashya Rasa, Madhura, Katu Vipaka, Sheeta Virya, Kaphapittahar* properties which not only help to breakdown the etiopathogenesis of disease but also pacifies vitiated doshas and bring homeostasis. Along with this *Yashtyadi Ghrita* enhances *Agni* (digestive fire). *Yashtyadi Ghrita* will promote appetite; enhance bioavailability of nutrients and acts as anabolic agent, thus increasing quantity of diet to be taken and best utilisation of it to form body tissues. Thus, assimilation of nutrients will be better due balanced *Agni* and there will be rapid recovery with formation of *Prasahasta Dhatu*. Various clinical & experimental trial of individual drugs used in the preparation of *Yashtyadi Ghrita* shows antimicrobial activity[19] bio-availability

enhancer,[20] immunomodulatory activity,[21] anti-inflammatory,[22,23] anabolic, antioxidant,[24,25] adaptogenic and rejuvenator activity.

AIMS & OBJECTIVES

The present study is planned with the following aims and objectives: -

- To evaluate the therapeutic effect of *YASHTYADI Ghrita* in the management of Balsosha (Marasmus)
- To provide relief in the symptoms of Balsosha (Marasmus)
- To collect literature of Balsosha (Marasmus)in ayurveda & modern textbook.

Hypothesis

H_0- *Yashtyadi Ghrita* is not efficacious in the management of Balsosha (Marasmus)

H_1- *Yashtyadi Ghrita* is having clinically efficacy in the management of Balsosha (Marasmus)

MATERIAL & METHODS

- For present study two types of materials will be utilized as furnished below: -
- **Literary review**- Literary references will be collected from
    - Ayurveda classics
    - Commentaries
    - Modern literature
    - Search engine like Pubmed, Google Scholar, Ayush research portal and Internet etc.
    - All of these will be analyzed to explain literary aspect of Balsosha w.s.r to PEM.

Clinical Study

Selection of cases- For this clinical study, Patients (age group of 0 to 5 years of both sex) will be selected from O.P.D. and I.P.D. of University college of *Ayurved* Hospital & Satellite *Ayurvedic* Hospital, Magra Punjala, Jodhpur, Rajasthan, India and surrounding villages if needed on the basis of clinical examination and investigation.

Research Design- Open Label Single Arm Study

Participants- Balsosha affected children of both sex

Duration of study-60 days

Follow up – All Children will be called for follow up every fortnightly i.e., 15 days, 30 days, 45 days,60 days and after one month of completion of study.

Inclusion Criteria

- Age group of 1 to 5 years of both sexes
- Patients of Balsosha (Marasmus) satisfied IAP criteria grade I & II.
- History of growth failure
- Patients with clinical features of Balsosha (Marasmus) mentioned in Ayurveda and modern textbooks.

- Parents or caretaker willing to participate in the clinical trial.
- Not planning to leave the study area for the coming 04 months

Exclusion Criteria

Patients Presented with the following diseases will be excluded from registration-

- Children with age below 1 year and more than 5 years.
- Children suffering from severe malnutrition (IAP criteria) with no appetite and complications like hypothermia, respiratory distress (presence of tachypnea, intercostal recession), extensive skin lesion/infection, lethargic, unconscious, presence of convulsions, severe dehydration based on history & clinical signs, any condition that requires an infusion or NG tube feeding and blood hemoglobin less than 08 gm/dl.
- Kwashiorkor
- Tuberculosis
- Juvenile Diabetes
- Chronic Diarrhea
- Rickets
- Chronic Liver disorder
- Malabsorption syndrome

Discontinuation Criteria

- Any Acute illness
- Parents refusing to continue even after proper counseling.

Untoward Evaluation Criteria

- To record adverse reaction an untoward reaction assessment form will be develop and all such adverse reactions will be note down.

Sample Size

- There are several methods used to calculate the sample size depending on the type of data or study design. As our study is equivalence trial to prove efficacy of *Yashtyadi Ghrita* in the management of malnourished children. We used following formula: -

$$N= Z^2PQ/d^2$$

Where N is Size of population

Z-Standard Normal deviation

P- Expected Prevalence of disease

Q- Level of Significance (Q=1-P)

d- Degree of precision or amount of tolerable sampling error

Under 5-year percentage of malnourished child in Rajasthan was 39 % reported from past studies at 5 degrees of precision. Thus, putting all these values in the above formula sample size comes out to be

366 with 95% level of significance. The calculated size from above formula is quiet high as compared to 100-200 (average-150) patients in outdoor of Dr. S. R. RAU, Hospital, Jodhpur. Therefore, if study population is finite or too small then corrected revised sample size is

$$n = \frac{m}{1 + \frac{m - 1}{N}}$$

Where N is Size of finite population of

m is calculated sample size

n is corrected revised sample size

Thus, putting all these values in the above formula sample size comes out to be 107.Therefore, present study is proposed with sample size of 110 malnourished children.

TRIAL DRUG

यष्ट्याह्व पिप्पलीलोध्रपद्मकोत्पलचन्दनैः।

तालीसशारिवाभ्यां च साधितंशोषजित् घृतम्।। अ0सं0उ0 2/50

For present study *Yashtyadi Ghrita* is selected which is mentioned in the management of Balsosha in *Balaupcharaniya* chapter of *Uttarasthan* of *Astanaga Samgrha.*

YASHTYADI GHRITA

S.No.	Drugs name	Latin Name	Used Parts	Quantity
1.	*Madhuyesti*	Glycyrrhiza glabra Linn.	Roots	1 part
2.	*Pipplai*	Piper longum Linn.	Fruits	1 part
3.	*Lodhra*	Symplocos Racemosa Roxb.	Twak	1 part
4.	*Padamakh*	Prunus Cerosides D. Don.	Beejmajja	1 part
5.	*Kamal*	Nelumbo Nucifera Gaertn	Seeds	1 part
6.	*Chandan*	Santalum Album Linn.	Kandasar	1 part
7.	*Talispatra*	Abies webbiana Lindle	Leaves	1 Part
8.	*Sariva*	Hemidesmus Indicus R. Br.	Roots	1 part
9.	*Ghrita*	As required		QNS

Drug will be used in the form of ghrita for easy administration and palatability to the children. This will be given in a dose of body weight, twice a day for 60 days duration. This drug will be prepared in pharmacy of University College of Ayurved, Dr.S.R. Rajasthan Ayurved University, Jodhpur, Rajasthan.

GROUPING AND POSOLOGY

Name of Drug	*Yashtyadi Ghrita*
Number of patients	110
Duration of Drug Trail	60 Days
Duration	Twice a day
Dose	Calculated by Fried up to 1 yr. then young formula
Anupan (Vehicle)	Milk
Route	Oral
Type of study	Single Arm Open Level Study

Drug & Dosage: -

Standard Dose of Ghrita- 1 Pala (48 Gram = 48 ml) Sharangdhara Samhita

Dose of ghrita in child from 0 to 5 yrs. is calculated by the use of from 1 year up to 5 years from young formula.

S.No	**Age in years**	**Dose of *Yashtyadi Ghrita***	**Energy (Calories)** **1 gm fat = 9 calories**
1.	1 years	3.69 ml	33.21 calories
2.	2 years	6.85 ml	61.65 calories
3.	3 years	9.6 ml	86.4 calories
4.	4 years	12 ml	108 calories
5.	5 years	14.11 ml	126.99 calories

Diagnostic Criteria - I.A.P. Criteria for diagnosis of PEM will be adopted.

Assessment Criteria

The assessment of progress will be done by regular fortnightly observation and examination of the patients and the progress will be recorded on the prescribed performa.

Subjective assessment

Assessment of clinical features *(Arochaka, Jwara, Pratishyaya, Kasa, MukhaSnigdhata, MukhShwetata, Netra Snigdhata, Netra Shwetata, Shwasa, and Shotha)* depending on the severity was done on four-point scale-

S.No.	**Clinical Features**	**Grading**
1.	***Arochaka* (Appetite)**	
	Normal appetite	0
	Unwilling to take food but eats	1
	Unwilling to take food, intake of food decrease	2

	No interest to take food	3
2.	***Jwara* (Fever)**	
	No fever, temperature lie between 98 to 99˚F	0
	Either mild fever, temperature lies between 99 to100˚F or frequency up to one episode/15day	1
	Either moderate fever, temperature lies between 100 to 103˚F or frequency two episode/15 day	2
	Either high fever temp >103˚F or frequency more than 2 episode/15day	3
3.	***Pratishaya* (Coryza)**	
	No nasal discharge (No Nasa Srava)	0
	Either nasal discharge once only in morning or frequency up to 1/15day	1
	Either nasal discharge both morning & evening or frequency 2/15 days	2
	Continuous nasal discharge	3
4.	***Kasa* (Cough)**	
	No cough	0
	Occasional cough frequency up to 1/15 day	1
	Either continuous cough with moderate pain or frequency 2/15 day	2
	Either continuous cough with severe pain or frequency more than 2/15 day	3
5.	***Mukha-snigdhata* (Face smoothness)**	
	No scratch line	0
	Slight scratch line	1
	Line not so prominent	2
	Prominent scratch line	3
6.	***Mukha-shwetata* (Facial Pallor)**	
	No facial pallor	0
	Mild facial pallor with intact lustre	1
	Facial pallor with lost lustre	2
	Severe facial pallor with pale palmer crease	3
7.	***Netra snigdhata* (Sclera)**	
	Normal sclera with normal tear secretion	0
	Increase whiteness of sclera and tear secretion w/o collection of whitish wastes	1

	Increase whiteness of sclera and tear secretion with little collection of whitish wastes	2
	Bright white eye with large collection of whitish waste	3
8.	***Netra shwetata* (Anaemia)**	
	No pallor of palpebral conjunctiva	0
	Slightly pale conjunctiva w/o pallor of face	1
	Very pale conjunctiva with apparent facial pallor	2
	Pale conjunctiva with pale face and palmer crease	3
9.	***Shwasa* (Dyspnoea)**	
	No dyspnoea or dyspnoea on more than accustomed work/play	0
	Dyspnoea on accustomed work/ play	1
	Dyspnoea while doing less than accustomed work/ play	2
	Dyspnoea at rest	3
10.	***Shotha* (Periorbital oedema)**	
	No oedema	0
	Swelling in one particular region like periorbital	1
	Oedema in the two different site like pedal and periorbital	2
	Generalized oedema or ascites	3
11.	***Kesh Vikriti* (Hair Change)**	
	No hair change	0
	Sparse and coarse /silky hair	1
	Sparse altered texture and depigmented	2
	Sparse altered texture and pigmentation easily pluck able	3
12.	***Sosha*** (Emaciation)	
	No emaciation or loss of fat in any part of body	0
	Loss of fat in axilla / groin	1
	Loss of fat from abdominal wall & gluteal region	2
	Loss of fat from chest wall & back	3

Objective assessment

The objective assessment will be done as follows-

- **Physical Examination**
    - Weight for age criteria

- Height in cm
- Head Circumference in cm
- Chest Circumference in cm
- Mid Arm Circumference (M.A.C) in cm.
- Skin fold thickness (S.F.T.) in cm or mm

- **Laboratory Investigation**
  - Complete Blood Count
  - ESR
  - Total Serum Protein (TSP)
  - Albumin /Globulin Ratio (A/G Ratio)

OBSERVATION & RESULT –

Assessment parameters will be subjected to Univariate and multivariate analysis using Statistical Package for Social Sciences (SPSS) with appropriate statistical methods.

The data will be analysed by using paired t-test for objective parameters and 1-Sample Wilcoxon rank sum test, for subjective parameters.

ADVERSE DRUG EVENTS

All adverse events observed or reported by patients will be appropriately recorded with information about severity and possible relation to the study medication. Any serious adverse effects will be notified immediately to the study monitor.

Protocol of Research

A. Fulfillment of inclusion criteria

B. The guardians of the patient will be pre informed about the trial drug & its effects, duration of the study etc.

C. Registration of Patient

D. Written informed consent will be taken from patient before stating trial.

E. On first visit, a detail history will be obtained from guardians. Detailed information will be recorded in a Performa prepared on the basis of Ayurvedic & modern parameters.

F. The patients under falling in inclusion criteria will be thoroughly examined.

G. The blood investigations will be done before the start and after the completion of the project.

H. Follow-up and monitoring - All Children will be called for follow up every fortnightly i.e. 15 days, 30 days, 45 days,60 days and after one month of study. Any discomfort or untoward side effects will be noticed.

PREVIOUS RESEARCH WORK

NIA, Jaipur

I. Raghvesh Sharma 1992 Balsosha mein balsoshahar rasayan ka chikitsatmak adhyaana

II. Shambhu Dayal Sharma, 1997, Balsosha par baladi yoga ke prabhav ka chikisatmak adhyana

III. Bhagwan Sahai Sharma, 1998, Balsosha par katipaya dravyon ke prabhav ka chikitsatmak adhyayana

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IX. Jitesh Verma 2010, A Clinical study of Vidarikandadi Yoga in the management of Balshosha w.s.r. to Marasmus

X. Mahapatra Arun 2014; A Community based study to evaluate the efficacy of Poshatika syrup on the nutritional morbidity status of children w.s.r to Protein Energy Malnutrition

XI. Sharma Vedprakash 2021, A Community Based Study to Evaluate the Efficacy of Chaturjatadi Sambharaka on the Nutritional Status of Childrenwith Balshosha w.s.r. to Protein Energy Malnutrition"

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XIII. Prem Prakash Vyas, 1991, Study on the efficacy of Shiva modak & Yapana Basti in the management of Balsosha wsr to marasmus

XIV. Nirali Doshi, 2011, A clinical study on Samvardhan Ghrit and shastikshali pinda sweda in the management of karshya in children.

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Himachal University, Shimla

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XVII. Kumara Shiksha, 2017; A clinical study to evaluate the effect of Kshirbala taila Basti in the management of Karshya in school going children

Uttarakhanda Ayurved University, Dehradun

XVIII. Gandhi Vishal, 2019; Randomized controlled clinical study of Vidarikandadi Churna on karshya in Children

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18. Updhyaya U; Ashtanga Hridaya edited with Vidyotini Hindi Commentary by Kaviraj Atridev Gupta published by Chaukhambha Sanskrit Sansthana, Varanasi, Uttartantra Balamaya Pratishedhiya adhyaya 2/50-51, Page No.459
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The proposed research work will be presented in the form of thesis in the following format:

- Benediction
- Acknowledgement
- Introduction
- Review of Literature
    - Ayurvedic review
    - Modern review
- Drug review
- Clinical study
- Materials and Methods
- Observations and Results
- Discussion
- Summary
- Conclusion
- Bibliography